

CLAIMS

1. A multilayer dosage form composed of

5 a) a neutral core,

b) an inner coating of a methacrylate copolymer

10 c) an outer coating of a copolymer which is composed of 40 to 95% by weight free-radical polymerized C₁- to C₄-alkyl esters of acrylic or of methacrylic acid and 5 to 60% by weight (meth)acrylate monomers having an anionic group in the alkyl radical,

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characterized in that

20 the inner coating consists substantially of a methacrylate copolymer which is composed of at least 90% by weight of (meth)acrylate monomers having neutral radicals, has a minimum film-forming temperature as specified in DIN 53 787 not exceeding 30°C, and comprises the pharmaceutical active substance in bound form.

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2. The multilayer dosage form as claimed in claim 1, characterized in that the methacrylate copolymer of the inner coating is polymerized from 25-35% by weight methyl methacrylate, 75 to 65% by weight ethyl acrylate and, where appropriate, up to 10% by weight other vinylically polymerizable monomers, in particular (meth)acrylate monomers with polar or ionic radicals, where the proportionate amounts add up to 100% by weight.

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35 3. The multilayer dosage form as claimed in claim 1 or 2, characterized in that the active substance/polymer ratio of the inner layer is from

20:1 to 1:20.

4. The multilayer dosage form as claimed in one or more of claims 1 to 3, characterized in that the outer coating consists substantially of a (meth)acrylate copolymer of 40 to 60% by weight methacrylic acid and 60 to 40% by weight methyl methacrylate or 60 to 40% by weight ethyl acrylate.
5. The multilayer dosage form as claimed in one or more of claims 1 to 3, characterized in that the outer coating consists substantially of a (meth)acrylate copolymer of 20 to 40% by weight methacrylic acid and 80 to 60% by weight methyl methacrylate.
6. The multilayer dosage form as claimed in one or more of claims 1 to 3, characterized in that the outer coating consists substantially of a (meth)acrylate copolymer of 20 to 34% by weight methacrylic acid and/or acrylic acid, 20 to 69% by weight methyl acrylate, 0 to 40% by weight ethyl acrylate and, where appropriate, 0 to 10% by weight further vinylically copolymerizable monomers, with the proviso that the glass transition temperature of the copolymer as specified in ISO 11357-2, subsection 3.3.3, does not exceed 60°C.
7. The multilayer dosage form as claimed in one or more of claims 1 to 3, characterized in that the outer coating consists substantially of a (meth)acrylate copolymer consisting of 10 to 30% by weight methyl methacrylate, 50 to 70% by weight methyl acrylate and 5 to 15% by weight methacrylic acid.
8. The multilayer dosage form as claimed in one or

more of claims 1 to 7, characterized in that it comprises an active substance from the active substance classes of aminosalicylates, of sulfonamides or of glucocorticoids.

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9. The multilayer dosage form as claimed in claim 8, characterized in that it comprises the active substance 5-aminosalicylic acid, olsalazine, sulfalazine, prednisone, prednisolone or budesonide.

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10. The multilayer dosage form as claimed in one or more of claims 1 to 7, characterized in that it comprises an active substance from the active substance classes of enzymes, peptide hormones, immunomodulatory proteins, antigens, antibodies or of oligonucleotides.

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11. The multilayer dosage form as claimed in claim 10, characterized in that it comprises the active substance pancreatin, insulin, human growth hormone (hGH), corbaplatin, intron A, calcitonin, cromalyn, interferons, calcitonin, granulocyte colony stimulating factor (G-CSF), interleukin, parathyroid hormones, glucagon, pro-somatostatin, somatostatin, detirelix, cetrorelix, vasopressin, 1-deaminocysteine-8-D-arginine-vasopressin, leuprolide acetate or an antigen which has been isolated from grasses or other plants such as, for example, rye, wheat, barley, oats, bermuda grass, horsetail, sycamore, elm, oak, plane tree, poplar, cedar, horsetail, thistles.

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12. The multilayer dosage form as claimed in one or more of claims 1 to 6, characterized in that the values for the percentage release of active substance in a hypotonic and an isotonic release medium based on phosphate buffer pH 6.8 do not

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differ from one another at any time in the period
from 1 to 5 hours by more than 10%.